

DeRoyal Industries, Inc.
Disposable Limb Holder

K 963476

510(k) Summary

JAN 22 1997

**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
UPON WHICH
AN EQUIVALENCE DETERMINATION COULD BE BASED**

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc.
ADDRESS: 200 DeBusk Lane
Powell, TN 37849

TELEPHONE: (423) 938-7828
CONTACT: Camille Matlock
DATE OF PREPARATION: August 30, 1996

DEVICE NAMES

NAME: DeRoyal Industries, Inc. Disposable Limb Holder
COMMON/USUAL NAME: Disposable Limb Holder
CLASSIFICATION NAME (if known): Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETING DEVICES

J.T. Posey Company
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Disposable Limb Holder is a protective restraint device that is intended for medical purposes to limit limb movements thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Disposable Limb Holder is designed similar to those marketed by other manufacturers. The Disposable Limb Holder is primarily comprised of a kodel, nylon, flannel or blue purr material. The straps are made of white webbing. The fasteners are made of hook and loop or steel nickel plated buckles.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Disposable Limb Holder is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit limb movements thereby enabling examination or protection of the patient or others. The Disposable Limb Holder can be used with a gurney, bed, or stretcher.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	Primarily comprised of kodel, nylon, flannel or blue purr material. The straps are made of white webbing. Fasteners include hook and loop or buckles.	Same
Size	Universal	Same
Vehicles for Attachment	Gurney, Bed, or Stretcher	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly to moderately agitated or disoriented	Same